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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,188	12/01/2003	Yoke Min Sin	2500-000017	9843
27572	7590 08/27/2004		EXAMINER	
HARNESS, DICKEY & PIERCE, P.L.C.			FORD, VANESSA L	
P.O. BOX 828	D HILLS, MI 48303		ART UNIT PAPER NUMBER	
	5 111525, 111 105 05		1645	
			DATE MAILED: 08/27/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	10/725,188	SIN ET AL.				
Office Action Summary	Examiner	Art Unit				
	Vanessa L. Ford	1645				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIREMONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠ Responsive to communication(s) filed on <u>01 December 2003</u> .						
2a) This action is <b>FINAL</b> . 2b) This action is non-final.						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4) Claim(s) 1-47 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) is/are allowed. 6) Claim(s) is/are rejected. 7) Claim(s) is/are objected to.  8) Claim(s) 1-47 are subject to restriction and/or election requirement.						
Application Papers  9) The specification is objected to by the Examiner.						
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119  12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No.  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)						
Notice of Draftsperson's Patent Drawing Review (PTO-948)     Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)     Paper No(s)/Mail Date	Paper No(s)/Mail Date 5)  Notice of Informal Pate 6) Other:	 ent Application (PTO-152)				

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## **DETAILED ACTION**

## **Election/Restriction**

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-22, 27-36 and 45-47 are drawn to a vaccine, classified in class 424, subclass 184.1.
  - II. Claims 23-26 are drawn to a method of making an oral vaccine, class 435, subclass 41.
  - III. Claims 37-42 are drawn to a method for treating, classified in class 424 subclass 234.1.
  - IV. Claims 43-44 are drawn to a fish and edible product class 424, subclass429.

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- 2. Groups I and II are related as product and process of making. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.06(f)). In the instant case, the method of Group II can be used to make another protein that is materially distinct from the *Aeromonas hydrophila* major adhesion protein (AHMA).
- 3. Groups I and III are product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a material different process (MPEP 806.05(h). In the instant case the inventions of Group IV may be used for a number of different processes that are very much unrelated. For example, the product of Group I can be used to make antibodies.
- 4. Groups I and IV are different products. The inventions are patentably distinct, each from the other, because they are distinct products, which are different structurally and functionally.
- 5. Groups II and III are different methods. They differ because they have different goals, require different method steps and parameters.

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6. Groups II and IV are related as process of using and product used. The products of Group IV is not required for the method of Group II. The Groups are materially distinct and independent from each other as claimed.

- 7. Groups III and IV are product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a material different process (MPEP 806.05(h). In the instant case the inventions of Group IV may be used for a number of different processes that are very much unrelated. For example, the products of Group IV can be used as edible products for commercial sale.
- 8. Because these inventions are distinct for the reasons given and have acquired a separate status in the art because of their recognized divergent subject matter as shown by their different classification, restriction for examination purposes as indicated is proper. Moreover, in the absence of restriction it would place an undue search and examination burden on the examiner.
- 9. Applicant is advised that the reply to this requirement to be complete must include an election of invention to be examined even though the requirement be traversed (37 CFR 1.143).

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- 10. Applicant is reminded that upon that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).
- 11. The examiner has required restriction between product and process claims.

  Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is

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found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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12. A telephone call was made to CANTOR, BERNARD J. on August 19, 2004 to request an oral election to the above restriction requirement, but did not result in an election being made.

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## Conclusion

13. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov./">http://pair-direct.uspto.gov./</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford Biotechnology Patent Examiner August 19, 2004

SUPERVISORY PATENT EX. THE TECHNOLOGY CENTER 100.